REMARKS

Claims 23, 25-41, and 43-47 are now pending in the application, and claims 26-46 have been withdrawn from consideration. The Examiner has rejected claims 23-25 and 42-46. Applicants have cancelled claims 24 and 42, as they are now duplicative in light of amendments made to claim 23. Applicants also request clarification as to whether claims 43-46 are withdrawn or under consideration.

The amendments to the specification, claim 23, and new claim 47 are supported in the specification as filed. The stringent conditions (50% formamide, 5X SSC, at 42°C, for 12-16 hours) are provided in Alizon, Nature: 312:757-60 (1994). This reference is cited in the specification on page 19, lines 16-20. As all of the references in the specification are incorporated by reference (page 36, lines 5-10), Applicants have amended the specification to refer to these stringent conditions and enclose with this response a *Hawkins* declaration to support the amendment.

I. Written Description Rejection

The Examiner has rejected claims 23-25 and 42-46 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support in the specification. The Examiner argues that as previously set forth, the claimed invention is broadly directed toward purified HIV-1 variants that differ genetically in the *gag*, *pol*, and *env* coding regions from three known HIV-1 prototypes (e.g., IIIB, BRU, and ARV-2) by the specified amounts (e.g., 3.4% in Gag, 3.1% in Pol, and 13.0% in Env). The Examiner also acknowledges that the claims contain other limitations. Patient antisera recognizes

(1) the variant Gag, Pol, and Env proteins and (2) Gag, Pol, and Env proteins of HIV-1_{MAL}. The variants also contain the common genomic structural organization of HIV.

It is useful to compare the present application to a fairly recent Federal Circuit decision, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002). While the written description issue in that case was not decided, but was instead remanded to the district court for further consideration, the Federal Circuit elaborates on what types of situations might provide written description support for biotechnology inventions.

In that case, the claims were directed to nucleic acid probes that selectively hybridize to the DNA of *Neisseria gonorrhoeae*, when compared to a similar bacteria *Neisseria meningitides*. The patentee, Enzo, had identified three nucleic acid probes meeting the claim limitations and had deposited those probes. Enzo argued that the claims were supported by the written description because of the disclosed correlation of the function of hybridization with the bacterial DNA. *Id.* at 967. As strains of the two bacteria were publicly available and could be used to identify which probes would meet the limitations of the claims, the Federal Circuit stated that whether the claims were supported by the written description was a factual one and could not be decided against the patentee in summary judgment. In doing so, the Federal Circuit relied on the Written Description Guidelines issued by the U.S.P.T.O. The Guidelines state that written description can be met by

> Show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled

> with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Id. at 964 (quoting Guidelines, 66 Fed. Reg. at 1106).

The Federal Circuit continued by describing an example provided in the guidelines of claims to an isolated antibody to a known antigen, given the well defined structural properties of antibodies, the functional characteristics of antibody-antigen binding, and the high level of scientific understanding in that particular field. *Id.* It concluded, before remanding the case, that the written description requirement would be met for all of the patent claims "if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Id.* The Federal Circuit continued by stating "[b]ecause the claimed nucleotide sequences preferentially bind to the genomic DNA of the deposited strains of *N. gonorrhoeae* and have a complementary structural relationship with that DNA, those sequences, under the PTO Guidelines, may also be adequately described." *Id.* at 968.

Thus, the court remanded the case to determine "whether a reasonable fact-finder could conclude that the claimed sequences are described by their ability to hybridize to structures that, while not explicitly sequenced, are accessible to the public. Such hybridization to disclosed organisms may meet the PTO's Guidelines stating that functional claiming is permissible when the claimed material hybridizes to a disclosed substrate." *Id.*

Like *Enzo*, the present invention is defined by its relationship to other known structures. In the present case, the HIV-1 variant virus will bind to AIDS patient sera,

when that sera also binds to Gag, Pol, or Env polypeptides of the HIV-1_{MAL} virus deposited at the CNCM. Binding to AIDS patient sera was a well recognized technique for classifying virus antigens. *See* specification, page 16, lines 15-20 (citing *Chang* et al., Expression in Escheria coli of open reading frame gene segments of HTLV-III, Science 228:93-96 (1985)). As *Enzo* states, the question is whether a person of skill in the art would consider the subject matter of the claimed invention clearly described. As binding to AIDS patient sera was a recognized technique in the art, Applicants believe that the skilled artisans, familiar with this technique, would be able to envision the class of variants defined by binding to sera, in combination with the other limitations provided. Applicants assert that this combination of structural and functional features having a disclosed correlation between that function and a sufficiently described structure is sufficient to provide written description support for this invention.

In the Final Office Action, the Examiner states that "the skilled artisan would not reasonably conclude that applicants were in possession of any other HIV-1 variant," focusing on the "possession" aspect of written description. This requirement is being misconstrued—written description does not require physical possession of every member of the class of variants. In *Enzo*, for example, while the patentee had physical possession of several probes, it did not have as many as claimed. *Enzo* signifies that the Federal Circuit does not require physical possession of biotechnology inventions—but that merely describing the functional relationship between the members of the class and other known structures may suffice.

Additionally, the Examiner states that "the skilled artisan could not reasonably predict what the precise nucleotide sequence of any other isolate will be." This too stringently states the requirements for written description. In *Enzo*, it does not appear that a skilled artisan would be able to predict the exact nucleotide sequences of the probes, but that the sequences could only be determined after the binding experiments. *See Enzo*, at 966. Clearly, this was not a dispositive issue for the Federal Circuit and should not be here as well. *Id.*

Furthermore, as described in the Guidelines, the physical structure of the viral genome is described and claimed in the present case. In the Guidelines, the PTO stated that the "well defined structural properties of antibodies" were a factor in support of written description. Likewise, the organization of the viral genome as disclosed and claimed supports the written description of the claimed invention.

Finally, Applicants have amended claim 23 to recite that "HIV-1 variant virus can be detected by stringent hybridization (50% formamide, 5X SSC, at 42°C, for 12-16 hours) with a DNA probe comprising the genomic cDNA of HIV-1_{MAL}." These stringent conditions are provided in Alizon, Nature: 312:757-60 (1994). This reference is cited in the specification on page 19, lines 16-20. As all of the references in the specification are incorporated by reference (page 36, lines 5-10), Applicants have amended the specification to refer to these stringent conditions and provided a *Hawkins* declaration to support the amendment.

Thus, this provides a further functional relationship to a known structural element. Therefore, Applicants assert that the claimed variant virus is adequately supported by the written description.

II. Prior Art Rejection

The Examiner has again rejected the claims as anticipated by or obvious over *Meyers* (1990), as the Examiner alleges that the claims are not entitled to the benefit of the earlier filed U.S. and French applications. *Myers* was published after the U.S. and French priority dates (U.S. Appln. Ser. No. 07/038,330, filed April 13, 1987, and French Appln. 86401380.0, filed June 23, 1986). Applicants submit that the specification fulfills the written description requirement and, thus, the *Myers* article, published in 1990, cannot be prior art.

III. Conclusion

Applicants respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the claims in condition for allowance. Applicants submit that the proposed amendments of the claims do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the Final Action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment

would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 16, 2004

By: Rebecca M. McNeill
Rebecca M. McNeill
Reg. No. 43,796

PATENT
Customer No. 22,852
Attorney Docket No. 02356.0011-06000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Marc ALIZON et al.	)	Group Art Unit: 1648
	)	
Application No. 09/041,975	)	Examiner: Jeffrey S. Parkin
	)	
RCE Filed: April 8, 2003	)	
	)	
For: VARIANT OF LAV VIRUSES	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Declaration Pursuant to In Re Hawkins, 179 U.S.P.Q. 157 (C.C.P.A. 1973)

I, Rebecca M. McNeill, do hereby declare and say that:

1. The specification is amended to provide stringent hybridization conditions of 50% formamide, 5X SSC, 42°C, for 12-16 hours. These stringent conditions are disclosed in Alizon, Nature: 312:757-60 (1994) (describing hybridization "for 12-16 h in stringent conditions (50% formamide, 5xSSC, 42°C)" in the legend of Figure 2). This reference is cited in the specification on page 19, lines 16-20, immediately at the end of a sentence referring to stringent hybridization conditions. As all of the documents cited in the specification are incorporated by reference (page 36, lines 5-10), Applicants have amended the specification to refer to these stringent conditions.

2. The stringent conditions added to the specification are the same as those that are characterized as "stringent conditions" by the Alizon article, which is cited and incorporated by reference in this application.

3. I further declare that all statements made herein of my own knowledge are true; that all statements made on information and belief are believed to be true; that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 16, 2004

By: Rebecca M. McNeill
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